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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,077	06/23/2003	Stephen Suffin	10701-006-999	1225

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,077	SUFFIN, STEPHEN	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-42 and 50-60* is/are pending in the application.

4a) Of the above claim(s) *57-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-42 and 50-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 1/23/08 wherein claims 1-39 and 43-49 are canceled and claims 40 and 54 are amended.

Note: Claims 40-42 and 50-60 are pending.

RESPONSE TO APPLICANT'S AMENDMENTS/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 1/23/08 to the rejection of claims 40-42 and 50-56 made by the Examiner under 35 USC 102 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 10/26/07 and those set forth below.

102 Rejection

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 40-42 and 50-56 under 35 USC 102(b) as being anticipated by Wenk et al (The Journal of Neuroscience, October 1994, Vol. 14, No. 10, pp. 5986-5995) is MAINTAINED for reasons of record in the office action mailed 10/26/07 and those set forth below.

In summary, Applicant makes the following assertions. The claims are not anticipated because the Examiner has not recognized that the Applicant's multivariate outcome measurement comprise univariate Z scores which are not taught in Wenk et al which merely measures absolute EEG power in the frontal or parietal brain region. Wenk et al's presentation of absolute power data does not anticipate Applicant's

multivariate outcome measurements. Applicant refers to paragraph [0063] of the specification which discloses that absolute power is a raw univariate measurement. Wenk et al does not teach a method to determine drug efficacy by comparing differences between multivariate EEG data, instead the document relies on histological procedures to provide evidence of drug efficacy. In addition, Applicant asserts that the Examiner has failed to recognize that 192 IgG-saporin is a toxin, not a medication that is consistent with Applicant's definition of a medication.

Applicant's arguments are not persuasive for the following reasons. First, it should be noted that the claims are given their broadest interpretation consistent with the specification which must also be consistent with the interpretation that those skilled in the art would reach. Thus, it is recognized (inherent) that various measure are taken in order to obtain the multivariate values because throughout the Wenk et al document, multiple date is obtained for the subjects during various tests (i.e., the behavioral testing involved various choice trials for each subject (age 5987, ''T-maze alternation task'); the step-through passive avoidance testing involved various trials for the same subject (pages 5987-5988, 'Step-through passive avoidance'); and the electrophysiology measure were obtained for each subject using various EEG recordings using Fourier transformation of ten two second readings for each daily session which was digitized (page 5988, 'Electrophysiology'). The electrophysiological data obtained is analyzed, a mean value is obtained and values are set forth for the delta, theta, alpha, and beta (Figure 2, page 5989). Thus, based on the fact that various outcome measurements

are obtained that involve obtaining multiple data at the same and different points, it is inherent that multivariate outcome measurements are encompassed by Wenk et al.

In regards to Applicant's assertion that Wenk et al does not teach a method to determine drug efficacy and that 192 IgG-saporin is a toxin, not a medication, the assertions are non-persuasive. While the patients of Wenk et al were administered varying amounts of 192 IgG-saporin, it is noted that according to Wenk et al (see Summary, page 5986 and Figure 2, page 5989), the EEG recordings were obtained from the lesioned rats before and during treatment with scopolamine (see Summary, page 5986 and Figure 2, page 5989). Thus, while a toxin is used, the scopolamine is used treating the subjects. Hence, it is inherent that scopolamine would be the medication administered to the subjects. Furthermore, based on information well known in the art, for example, on healthline.com (site is disclosed below)

http://www.healthline.com/multumcontent/scopolamine?utm_medium=ask&utm_source=smart&utm_campaign=article&utm_term=Scopolamine&ask_return=Scopolamine

scopolamine is an anti-cholinergic *medicine* that has many effects in the body including decreasing the secretion of fluids, slowing the stomach and intestines, and dilation of the pupils. Scopolamine is used to relieve nausea, vomiting, dizziness associated with motion sickness, and recovery from anesthesia and surgery. In addition, scopolamine may also be used in the treatment of Parkinsonism, spastic muscle states, irritable bowel syndrome, diverticulitis, as well as other conditions. Thus, based on what is known in the art about scopolamine and its use in Wenk et al, it is inherent that it is a medicine. Hence, the rejection is deemed proper.

WITHDRAWN CLAIMS

3. Claims 57-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

NEW GROUNDS OF REJECTION

112 Rejections

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 40-42 and 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because of the phrase 'under conditions such that said difference determines said medication efficacy'. In particular, the phrase is ambiguous because it is unclear what particular conditions Applicant is referring to that are compatible with the instant invention. In addition, it is unclear what particular differences Applicant is referring to since one could have a situation wherein the average value does not change, but there is a difference in, for example temperature, pH, Applicant's response to multiple exposure to the same stimulus/medication.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/

D. L. Jones
Primary Examiner
Art Unit 1618

April 11, 2008